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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.				
10/580,665	03/27/2007	Daisuke Macjima	U 016319-1	5022				
140 LADAS & PARRY LLP 26 WEST 61ST STREET NEW YORK, NY 10023	7590 01/06/2010		<table border="1"><tr><td>EXAMINER</td></tr><tr><td>DEGUIRE, KATHERINE E</td></tr></table>		EXAMINER	DEGUIRE, KATHERINE E		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

nyuspatactions@ladas.com

Office Action Summary

Application No.

10/580,665

Applicant(s)

MAEJIMA ET AL.

Examiner

KATHERINE DEGUIRE

Art Unit

1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 21-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 21-30 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SI/200)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____
- Paper No(s)/Mail Date 2008/03/03, 2007/03/27

DETAILED ACTION

Claim Objections

Claim 23 is objected to because of the following informalities: Claim 23 recites the phrase "on a weight basis based on the whole first mixture material, in the first material mixture" The phrase "in the first material mixture" is redundant and should be removed. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,2,6,7, 11 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the term "oil and fat" component is unclear due to several possible interpretations of the term. It is unclear whether "oil and fat" refers to separate oil and a separate fat or an oil that serves as a fat. In other words, it is unclear if "oil and fat" refers to one ingredient or two. Example for baked product 1 in the specification discloses that the oil and fat is a palm oil or corn oil(p.17, line 27-29). Therefore, oil and fat is interpreted to be an oil for the purposes of this action.

Regarding claim 2, the term "highly purified whey protein isolate" is unclear because the applicant does not define "highly purified" in regard to whey protein isolate. Furthermore, it is unclear how whey protein isolate can be highly purified when whey protein isolate is the most highly purified form of whey available, with a protein concentration of 90%. It is unclear if the claim 2 means that the whey protein isolate is more highly purified than the conventional standard of 90% or if highly purified whey protein isolate refers to conventional whey protein isolate with a concentration of 90%.

Regarding claim 6 and 7, the term "trophicity enhancing component" is unclear because the applicant does not provide a definition or clear example for this term. Furthermore, there is no accepted definition of this term in the art or in everyday use. Claim 7 recites that the trophicity enhancing component is a calcium component or a iron component. For the purposes of this action, a trophicity enhancing component is interpreted to mean a calcium component or iron component.

Regarding claim 11, the term "cookie-like" is unclear because one of ordinary skill in the art would not know what is exactly is encompassed by this term. The applicant does not provide a definition for cookie-like. It is unclear exactly what properties of a cookie qualify a product to be cookie like. For example, it is unclear whether possessing flour as an ingredient, being round in shape, or containing sugar is sufficient to consider a product "cookie like".

Claim 24 recites the limitation "stirred oil and fat component." There is insufficient antecedent basis for this limitation in the claim. Specifically, independent claim 21 does not define the oil and fat component as stirred.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1,3-12, 21-25, and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim(US 4,442,132).

Regarding claim 1,4,10, 11, 21, 27, and 29, Kim discloses a high protein, low carbohydrate baked product. Kim discloses a general teaching for the ingredients of the baked product. They include, egg or egg albumin, 2-30% calcium caseinate, 15% wheat flour, and 3-40% minced nuts (column 1, line 50-60). This equates to a total protein concentration of:

Calcium Caseinate: Since Calcium caseinate is pure protein, a composition with 2-30% calcium caseinate contains 2-30% protein

Minced Nuts: Using hazelnuts from example II, hazelnuts contain 15% protein.

3-40% hazelnuts x 15% protein/wt hazelnut=0.45-6% protein

Wheat Flour: Wheat flour contains 13% protein

0-15% wheat flour x 13%protein/wt wheat flour=0-1.95% protein

Egg: Example II discloses the egg percentage as 48%. Egg contains 13% protein

48% egg x 13% protein/wt egg=6.24%

Adding the sources of protein together results in a protein range of 8.69% to 44.2%. The protein percentage was determined from the raw ingredients does not represent the protein percentage of the dry, finished product. However, one of ordinary skill in the art would expect the protein percentage of the dried product to be slightly higher due to the loss of water upon cooking. Regardless, the dried product contains a protein percentage of greater than 15%.

Example II discloses a composition and process for making nut cookies.

28.8 % Peeled and Minced hazelnuts

10.1% Lactitol monohydrate

0.8% Wheat flour

2.2% Calcium caseinate

48.0% Egg, fresh

9.6% Lactitol

0.5% Kitchen salt

First the hazelnuts and lactitol monohydrate are blended and ground by means of an almond mill. The hazelnuts inherently contain oil and fat and a protein. Kim even states that the grinding should be performed gradually to prevent the loss of oil. Lactitol monohydrate is a sugar alcohol that serves as a saccharide.

Next, the calcium caseinate, egg, lactitol, and salt are whipped separately. This mixture contains fat from the egg. Lactitol serves as the saccharide. This mixture is blended with wheat flour and the hazelnut mixture that was pre ground.

Regarding claim 3, Kim does not specifically disclose an adult amino acid scoring pattern of 100. However, Kim discloses a baked good product with a protein concentration of at least 15%. One of ordinary skill in the art would expect the composition of Kim to have an adult amino acid scoring pattern of 100 absent clear and convincing evidence to the contrary.

Regarding claim 5, Kim teaches that suitable sugar substitutes are lactitol, sorbitol and xylitol (column 2, line 11-15).

Regarding claim 6 and 7, Kim discloses a calcium component of calcium caseinate(example II). A calcium component functions as a trophicity enhancing component.

Regarding claims 8, 9, and 28, Kim is silent regarding the stress value and chew work of the baked high protein product. However, Kim discloses a high protein baked product comprising the protein, oil and fat, and saccharide components of claim 1. Kim also teaches that the high protein baked product is made by same method as claim 1 and 21. Therefore, one of ordinary skill in the art would expect the composition

disclosed by Kim to have to claimed stress value and chew work properties absent any clear and convincing evidence to the contrary. Furthermore, Kim teaches that sugar alcohols such as sorbitol and xylitol disclosed in the invention produce soft baked good products.

Regarding claim 22 and 25, Kim teaches that the grinding and blending of the first mixture occurs by means of an almond mill. Kim also teaches using friction rollers for the final grinding step(example II). The rollers would inherently create heat from the friction.

Kim does not specifically disclose that the primary product is heated and melted before combination with the secondary material. However, one of ordinary skill in the art would expect the heat produced from the friction rollers to at least partially melt the primary product.

Regarding claim 23, Kim discloses the first mixture to contain 28.8 parts hazelnuts and 10.1 parts lactitol monohydrate. Hazelnuts contain 60 g of fat per 100g of hazelnuts. This means that that first mixture contains

$$28 \text{ parts hazelnut} \times 60 \text{ parts fat} / 100 \text{ parts hazelnut} = 17.8 \text{ parts fat}$$

$$17.8 \text{ parts fat} / (28.8 \text{ parts hazelnut} + 10.1 \text{ parts lactitol monohydrate}) = 46\%$$

Even though the fat content of is above the 27 to 35% claimed amount, Kim does disclose using a smaller percentage of nuts, including 3 to 40%. For example, a nut percentage as low as 3% equates to an oil and fat percentage of 15% for the first mixture. It would have been obvious to use a smaller percentage of nuts in order to decrease the fat percentage for a more healthful product. Kim also teaches that other

baking products such as cake can be made. Other baking products such as cakes would require different amount of fat depending on the nature of the product. It would have been within the ability of one of ordinary skill in the art to vary the fat percentage of different baked products through routine experimentation.

Regarding claim 24, Kim does not teach that second material mixture is prepared by adding a saccharide component to the stirred oil and fat component. Specifically Kim does not teach that the oil and fat component is stirred first before the addition of the saccharide. However, it would have been obvious to stir the oil and fat component(the egg) of the second material mixture in order to break up the yolk and help to homogenize the mixture. Commonly recipes for baked goods suggest beating eggs before mixing with dry ingredients such as saccharides.

Regarding claim 12 and 30, Kim teaches that the high protein baking product comprises fat sources of egg and minced nuts. According to example II, egg is present at 48% of the composition. Eggs contain 11g of fat per 100g of egg. Example II also discloses hazelnuts. Kim teaches that hazelnuts can be present in a concentration of 3 to 40%. Hazelnuts contain 60g fat/100g nuts.

Egg: $48\% \times 11\% \text{ fat/egg} = 5.28\%$

Hazelnuts: $40\% \times 60\% \text{ fat/hazelnut} = 24\%$

This equates to a maximum fat percentage of 29%. However, the fat percentage is determined from the raw ingredients and not the dried finished product. One of ordinary skill in the art would expect the fat percentage of the dried product to be slightly higher in the claimed range of 32 to 39% due to the loss of water upon cooking.

Claims 2 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim in view of Titcomb(US 3,987,206).

Regarding claim 2 and 26, Kim does not disclose a protein component of whey protein isolate. However, Titcomb discloses a high protein bread product with added high protein whey powder(example I). One of ordinary skill in the art would expect high protein whey powder to be whey protein isolate since it is the most pure form of whey protein(90% protein). It would have been obvious to substitute some or all of the calcium caseinate for whey protein since whey contains a higher amount of protein and a lower amount of fat than calcium caseinate. Both ingredients are milk derivatives and would be easily interchangeable. Whey protein also contains a smaller amount of lactose than calcium caseinate and would be more easily tolerated by people with lactose allergies.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE DEGUIRE whose telephone number is (571)270-1136. The examiner can normally be reached on Monday through Friday 9-5:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on 571-272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Katherine E. DeGuire/
Examiner, Art Unit 1794

/KEITH HENDRICKS/
Supervisory Patent Examiner, Art Unit 1794